UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

CASSAVA SCIENCES, INC.,

Plaintiff,

v.

DAVID BREDT, GEOFFREY PITT, QUINTESSENTIAL CAPITAL MANAGEMENT LLC, ADRIAN HEILBUT, JESSE BRODKIN, ENEA MILIORIS and PATRICK MARKEY,

Defendants.

Case No. 1:22-cv-09409-GHW-OTW

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANTS DR. JESSE BRODKIN, DR. ADRIAN HEILBUT, AND DR. ENEA MILIORIS'S MOTION TO DISMISS CASSAVA'S SECOND AMENDED COMPLAINT

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PRELIMINARY STATEMENT

Cassava pleads no new facts to cure the deficiencies that mandated dismissal of its prior complaint. Rather, it recycles and rearranges its allegations and doubles down on pleading tactics this Court already rejected. In fact, the pleading merely betrays Cassava's singular commitment to suppress debate over simufilam and the "fabricated" data on which it is based. This campaign is unlawful and destined to fail, especially in light of the just-announced indictment of Dr. Hoau-Yan Wang for engaging in a years-long "scheme to fabricate and falsify scientific data" in grant applications to the National Institutes of Health related to simufilam "on behalf of himself and [Cassava]." 1

Challenging 75 statements by defendants (all but one on Twitter and 10 outside the scope of leave granted by the Court), Cassava resubmits many of the same exhibits it previously submitted, plus dozens of new but irrelevant exhibits (mostly its own press releases). As it did in its prior complaint, Cassava fails to direct defendants or the Court to the supposedly relevant sections of its 192 exhibits, spanning 1,929 pages. Thus, once again, Cassava leaves it to defendants and the Court to unpack its belligerent pleading.

Drs. Jesse Brodkin, Adrian Heilbut, and Enea Milioris (the "Dot.com Defendants") are three scientists who studied Cassava's extraordinary claims about simufilam, publicly questioned the research underlying those claims—including the foundational claim that simufilam binds with filamin-A protein in the brain—and shorted Cassava's stock based on their opinion that the underlying data was manipulated, if not entirely fabricated; hence, the "tag line" on Twitter "it's

¹ U.S. Department of Justice, Press Release (June 28, 2024), "Professor Charged for Operating Multimillion-Dollar Grant Fraud Scheme," https://www.justice.gov/opa/pr/professor-charged-operating-multimillion-dollar-grant-fraud-scheme; *see also* Cassava Press Release (June 28, 2024), https://www.cassavasciences.com/news-releases/news-release-details/cassava-sciences-issues-statement-former-science-advisor

all made up." In retaliation, Cassava has set out to punish Defendants with litigation costs and scare other would-be critics and witnesses, while contending with mounting pressure from investors and law enforcement over its failure to credibly defend its research, let alone explain the absence of original data underlying its scientific and clinical claims about simufilam.

Cassava fails to state a plausible defamation claim.

First, Cassava does not plead falsity. Cassava cannot contest that the factual predicate for all of the allegedly defamatory statements is either substantially true or irrefutable: the research papers underlying simufilam and simufilam's clinical research studies contain signs of data manipulation and fraud, including admitted errors and anomalies, which cannot be refuted because neither Cassava nor Dr. Wang preserved the original, raw data. And, based on the indictment of Dr. Wang, it now appears clearer than ever that no such data ever existed. (Infra Section II.)

Second, Cassava fails to plead actual malice. The allegations of actual malice are nearly identical to those alleged in the prior complaint and fail for the same reasons. The only new allegations concern sources and studies that post-date the Dot.com Defendants' initial critiques, and the Court already recognized that such allegations do not support an inference of actual malice. Nor can Cassava credibly claim recklessness, especially after the DOJ joined the chorus of critics and scientists to reach the same conclusions as the Dot.com Defendants. (Infra Section III.)

Third, the allegedly defamatory statements are nonactionable. Examining the challenged statements "in isolation," the Court previously determined that some were factual with a defamatory meaning, while recognizing that such determinations could change if the statements were examined in context. Now that Cassava has alleged additional context (including

additional portions of the threads in which they were posted), it is clear that the challenged statements are nonactionable either as pure opinion under *Gross* or scientific discourse under *ONY*. (*Infra* Section IV; *see also* Appendix 1, submitted herewith.)

For these reasons, the Dot.com Defendants respectfully submit that the SAC should be dismissed with prejudice.

BACKGROUND²

A. Cassava and Simufilam

Cassava is a publicly traded pharmaceutical company based in Texas and incorporated in Delaware, previously known as Pain Therapeutics. (SAC ¶¶ 12-13; Ex. 87.) Cassava is currently sponsoring clinical studies of an experimental new drug—simufilam—to treat patients with Alzheimer's disease. (*Id.* ¶¶ 28-30.)

According to Cassava, simufilam can improve brain health by targeting the filamin-A protein in the brain of Alzheimer's patients and reverting the protein to its "native, healthy conformation." (*Id.* ¶¶ 30-37.)

In 2017, Cassava filed an Investigational New Drug ("IND") application with the FDA and then proceeded to conduct "Phase 1", "Phase 2a", and "Phase 2b" studies over the next three years. (*Id.* ¶¶ 55-78.)

In October 2021, Cassava announced the initiation of its first Phase 3 trial, RETHINK-ALZ, "designed to evaluate the safety and efficacy of oral simufilam 100 mg over 52 weeks," involving approximately 800 patients. (*Id.* ¶¶ 84-85.) "Over 340 patients have completed" the

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² Citations herein to the "SAC" and "Ex." refer to the Second Amended Complaint (Dkt. 120) and 192 Exhibits thereto (Dkts. 121-1 to 126-32).

study, and "Cassava anticipates a top-line data readout for this study by approximately year-end 2024." (*Id.* ¶ 86.)

In November 2021, Cassava announced the initiation of its second Phase 3 trial, REFOCUS-ALZ, "designed to evaluate the safety and efficacy of oral simufilam 100 mg and 50 mg over 76 weeks," involving approximately 1,100 patients. (*Id.* ¶¶ 87-88.) "Over 215 patients have completed" the study, and "Cassava anticipates a top-line data readout for this study by approximately mid-year 2025." (*Id.* ¶ 90.)

B. <u>Disputed Research and Missing or Non-Existent Data</u>

Cassava's claims about simufilam are based primarily on research by Dr. Hoau-Yan Wang, a professor at CUNY, and Dr. Lindsay Burns, Cassava's SVP of Neuroscience and the spouse of Cassava's CEO, Remi Barbier. (*See, e.g., id.* ¶ 558.)

1. Contested Findings from Simufilam's Phase 2b Trial and "Re-do"

In May 2020, Cassava disclosed negative findings from its "Phase 2b" clinical trials of simufilam. (*Id.* ¶¶ 62-65.) According to Cassava, the Phase 2b study showed "unnaturally high variability and other problems," and "served no useful purpose." (*Id.* ¶ 64.)³ In August 2020, Cassava sought to dismiss the study's findings as "anomalous and highly improbable," and Cassava's CEO said the Company was conducting a "comprehensive analysis" of the results, which he described as a "re-do." (*Id.*; Ex. 103 at 2.) One month later, in September 2020, Cassava reported that its "re-do" had found positive evidence of simufilam's "effects on biomarkers." (*Id.* ¶¶ 66-78, Ex. 104 at 2.)

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³ Press Release, "Top-line Results from a Phase 2b Study of PTI-125 in Alzheimer's Disease Does Not Meet Primary Endpoint," *Cassava Sciences* (May 15, 2020), https://www.cassavasciences.com/news-releases/news-release-details/top-line-results-phase-2b-study-pti-125-alzheimers-disease-does

However, Cassava later acknowledged that the "re-do" had been conducted by Dr. Wang, the Company's long-time consultant and collaborator,⁴ and Cassava does not (and cannot) allege otherwise in the SAC. *See Cassava Sciences, Inc. v. Bredt, et al.*, No. 22-cv-9409, 2024 WL 1347362, at *12 (S.D.N.Y. Mar. 28, 2024) (noting Cassava "does not allege that the reanalysis was not conducted by Dr. Wang's lab or that Dr. Wang is not affiliated with [Cassava]").

Moreover, on March 20, 2024, an Editor's Note was added to the non-peer reviewed preprint of the Phase 2b study, "in light of concerns about the credibility of claims by Wang and Cassava" raised by an FDA inspection report. (*See* SAC ¶¶ 66-78 (incorporating by reference results from Phase 2b study)⁵.) The Editor's Note contains a link to a report by *Science*, describing the FDA's finding that Dr. Wang and CUNY had no original records or data from Dr. Wang's purported "re-do" analysis of the Phase 2b study.⁶

2. Cassava's Admissions of Errors and Absent Data

In August 2021, Defendants Dr. David Bredt, a neuroscientist and former executive at Eli Lilly and Johnson & Johnson, and Dr. Geoffrey Pitt, a cardiologist at Weill Cornell Medicine, submitted a Citizen Petition to the FDA.⁷ The Citizen Petition described "grave concerns about

⁴ Dave Michaels and Joseph Walker, "SEC Investigating Cassava Sciences, Developer of Experimental Alzheimer's Drug," *The Wall Street Journal* (Nov. 17, 2021), https://www.wsj.com/articles/cassava-sciences-alzheimers-sec-investigation-11637154199

⁵ Wang, H., Pei, Z., Lee, K., Rojas, Y. G., Doehner, T., Puente, J., & Burns, L. H. (2021). "Effects of simufilam on cerebrospinal fluid biomarkers in alzheimer's disease: a randomized clinical trial." https://doi.org/10.21203/rs.3.rs-249858/v1

⁶ *Id.* (citing Piller, Charles, "'Damning' FDA inspection report undermines positive trial results of possible Alzheimer's drug," *Science* (March 11, 2024), https://doi.org/10.1126/science.z7wo4zp).

⁷ Cassava previously submitted the Citizen Petition (Dkt. 30-5) with the FAC. Although Cassava did not resubmit the Citizen Petition, it is integral to and incorporated by reference into the SAC. (*See* SAC Exs. 127, 129, 135, 143 (containing Cassava's responses to the Citizen Petition); *see also* SAC ¶ 22.c, 305, 566.) In addition, under Fed. R. Evid. 201, the Court may take judicial notice of the Citizen Petition and other documents previously submitted in this case, including the Dot.com Defendants' other publications, to consider "the statements the exhibits contain for the fact that they contain them." *See, e.g., Edwards v. Khalil*, No. 18-CV-5138 (CS), 2021 WL 5450207, at *4 n.3 (S.D.N.Y. Nov. 22, 2021).

the quality and integrity of the laboratory-based studies surrounding [simufilam] and supporting the claims for its efficacy." (Citizen Petition at 2.) The Citizen Petition asked the FDA to "halt the clinical studies" of simufilam "pending a thorough audit of the publications and data relied on by Cassava." (*Id.*)⁸

On September 3, 2021, in response to the Citizen Petition and criticism on Twitter, Cassava's President and CEO, Remi Barbier, issued a public statement, which acknowledged:

- "Cassava Sciences does not have its own laboratory facilities. We use other people's labs. For this reason, we don't have the original films or images for the Western blots in question. Those were generated by our science collaborator at CUNY, who is Prof. Wang. For this reason, I have respectfully requested that CUNY inquire thoroughly but expeditiously into the allegations targeting Prof. Wang. I have also asked CUNY that its conclusionary findings be made available to the public." (Sept. 3, 2021 Tr. at 5);
- "There are legitimate forums to host scientific debate and make scholarly inquiries, and Twitter isn't one of them. Twitter storms can be entertaining to read, but entertainment is not evidence against the accused" (*id.* at 6);
- "right now I am specifically aware of visual errors in one publication and one poster presentation" (*id.* at 7);
- "[t]here may be more [errors] to come, I just don't know" (id. at 8);
- "the visual display of the data is not correct" (id.); and
- "You should not place undue reliance on . . . any scientific data we present or publish" (id. at 12).9

⁸ The FDA denied the Citizen Petition "solely on the grounds that [its] requests are not the appropriate subject of a citizen petition." (*See* Ex. 135.)

⁹ SAC Exhibit 129 (Dkt. 125-1) summarizes and provides links to the transcript and audio file of Barbier's September 3, 2021 statement; however, the links in Exhibit 129 appear to be broken. The incorporated transcript ("Sept. 3, 2021 Tr.") is available at the following link: https://www.cassavasciences.com/static-files/d4083c4d-b4ad-4e27-a93d-edaeff13b608

3. Scientific Journal Corrections, Retractions, and Investigations

Around the same time, peer-reviewed scientific journals that had published papers by Drs. Burns and Wang initiated investigations into the allegations of data manipulation or fabrication. (SAC ¶¶ 564, 627, Exs. 81, 133, 141, 190.) Among the many scientific journals that have issued corrections, expressions of concerns, or outright retractions of papers by Dr. Wang and Dr. Burns (*see id.*; *see also* Dkt. 87 at 4-6), three are particularly relevant:

First, on November 4, 2021, Cassava announced that the Journal of Neuroscience had "requested raw data" concerning a 2012 article (Ex. 173) by Drs. Burns and Wang and "determined that there was one duplicated panel . . . and a Corrigendum was requested and will be printed," but "[n]o evidence of data manipulation was found" (see Ex. 81 at 2). However, on December 16, 2021, the Journal of Neuroscience issued a follow-up "Expression of Concern" regarding the same 2012 article (Ex. 173), due to "concerns about Western blots . . . including those published with the article's erratum," and stated that the journal planned to "await the outcome of [CUNY's] investigation before taking further action." (See, e.g., SAC ¶¶ 564.a, Exs. 81, 173 (relying on 2012 article as integral to the SAC); see also SAC ¶ 280, 285, Exs. 33, 34 (challenging Statements 28 and 29, commenting on Expression of Concern).)

Second, in March 2022, the journal *PLoS One* retracted a 2008 article by Drs. Burns and Wang, after concluding that "[t]he data and comments provided did not resolve the concerns about the integrity and reliability of data presented in [the] article." This 2008 paper, claiming high affinity binding between naloxone and filamin A, was foundational to Cassava's subsequent

¹⁰ *JNeurosci*, "Expression of Concern: Wang et al., 'Reducing Amyloid-Related Alzheimer's Disease Pathogenesis by a Small Molecule Targeting Filamin A' [2012]" (Dec. 16, 2021), https://www.jneurosci.org/content/early/2021/12/16/JNEUROSCI.2306-21.2021

¹¹ *PLoS One*, "Retraction: High-Affinity Naloxone Binding to Filamin A Prevents Mu Opioid Receptor—Gs Coupling Underlying Opioid Tolerance and Dependence [2008]" (Mar. 30, 2022), https://doi.org/10.1371/journal.pone.0266627

claims in publications, patents, and in this case about the discovery and mechanism of simufilam—namely, its purported ability to bind filamin A. (*See* Ex. 170 at n.6, Ex. 172 at 114 (citing retracted 2008 paper); *see also* Ex. 64 (challenging Statement 59 commenting on and providing screenshot of retracted 2008 paper).)¹²

Third, in May 2022, the journal Neurobiology of Aging issued an "Expression of Concern" regarding a 2017 paper (Ex. 172) by Drs. Burns and Wang. (See Ex. 141 (press release describing and incorporating Expression of Concern); see also SAC ¶¶ 558.c, 564.c, 609, 379.)¹³ The editors noted that although they "did not find compelling evidence of data manipulation intended to misrepresent the results," they nevertheless found at least eight errors, and stated that the journal would make "a final decision as to appropriate corrective action" after the conclusion of CUNY's investigation of Dr. Wang. (Id.) Notably, the Expression of Concern revealed that "the authors," including Drs. Burns and Wang, had accepted the errors and "requested a corrigendum to correct these issues." (Id.) Like the retracted 2008 PLoS One article, these errors concerned the data underlying Cassava's "foundational" claim that simufilam could bind filamin A (see SAC ¶¶ 558.c, 564.c, 609, 379), which is the focus of the Dot.com Defendants' critique (see, e.g., FDA Letter at 3, Statements 1, 19, 21, 50, 69).

4. Investor Lawsuits, Government Investigations, and Media Coverage

Beginning in August 2021, several investors filed class actions against Cassava asserting securities fraud claims in connection with the development of simufilam. *See In Re Cassava*

¹² The Court "may properly take judicial notice of official records of the United States Patent and Trademark Office and the United States Copyright Office." *Telebrands Corp. v. Del Labs., Inc.*, 719 F. Supp. 2d 283, 287 n.3 (S.D.N.Y. 2010). *See* Burns, L., Wang, H-Y., Lin, N-H., Blasko, A., (2014), *Filamin A Binding Anti-Inflammatory and Analgesic*, (U.S. Patent No. 8,653,068 B2) U.S. Patent and Trademark Office. https://patents.google.com/patent/US8653068B2/en

¹³ Neurobiology of Aging, "Expression of Concern: Wang et al., (2017) PTI-125 binds and reverses an altered conformation of filamin A to reduce Alzheimer's disease pathogenesis. Neurobiol. Aging, 55:99-114" (May 2022), https://doi.org/10.1016/j.neurobiolaging.2022.03.012

Sciences, Inc. Securities Litigation, No. 21-cv-00751-DAE (W.D. Tex.). Shareholder derivative actions followed. See Zagami et al v. Barbier et al, No. 21-cv-00998-DAE (W.D. Tex.). In May 2023, the Court denied Cassava and the other defendants' motion to dismiss the securities action (dismissing only the claims against a deceased defendant). In re Cassava Scis, No. 21-cv-751, 2023 WL 3442087, at *1 (W.D. Tx. May 11, 2023). The securities action is currently in discovery, subject to a pending motion filed by Cassava in May 2024 to stay all merits discovery until the resolution of ongoing government investigations. (See id., Dkts. 162, 169.) Notably, on June 27, 2024, Cassava filed its Amended Answer in the securities action, which admitted to the corrections, retractions, and expressions of concern regarding simufilam's foundational research, described herein (see id., Dkt. 178 ¶¶ 33, 36-39, 42, 86, 154, 189, 357-358, 415-417, 423).

In November 2021, Cassava disclosed that "certain government agencies" had sought "corporate information and documents." (Ex. 82 at 77.) Later that month, the Wall Street Journal reported that the SEC was investigating allegations that Cassava had "manipulated research results of its experimental Alzheimer's drug," and Cassava's CEO confirmed that the allegations had also prompted inquiries by NIH. In July 2022, Reuters reported that Cassava was under criminal investigation by the DOJ relating to whether Cassava "manipulated research results" for simufilam. Since then, Cassava has disclosed in its SEC filings that these government investigations are "ongoing" and that it is "voluntarily cooperating and intend[s] to continue to cooperate." (*See, e.g.*, Ex. 82 at 77.)

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¹⁴ Dave Michaels and Joseph Walker, "SEC Investigating Cassava Sciences, Developer of Experimental Alzheimer's Drug," *The Wall Street Journal* (Nov. 17, 2021), https://www.wsj.com/articles/cassava-sciences-alzheimers-sec-investigation-11637154199

¹⁵ Marisa Taylor and Mike Spector, "Cassava Sciences faces U.S. criminal probe tied to Alzheimer's drug, sources say," *Reuters* (July 27, 2022), https://www.reuters.com/business/healthcare-pharmaceuticals/exclusive-cassava-sciences-faces-us-criminal-probe-tied-alzheimers-drug-sources-2022-07-27/

The media has covered extensively the allegations concerning Cassava and simufilam. ¹⁶ For example, the New York Times reported in April 2022 that it had "contacted nine prominent experts for comment about the scientific underpinnings of Cassava's trials" and "[a]ll said they did not trust the company's methods, results or even the premise underlying the drug's supposed effectiveness."

5. Cassava's Response to CUNY Report on Dr. Wang

On October 12, 2023, Cassava issued a press release (Ex. 162) responding to an article in *Science* that described and attached a "final" report by CUNY following the investigation of Dr. Wang that Cassava's CEO had publicly called for in September 2021 (*see* Sept. 3, 2021 Tr. at 5). According to Cassava's press release, the leaked report found "egregious misconduct" by Dr. Wang related to "internal recordkeeping failures" (Ex. 162 at 1) and further found that such "internal record-keeping failures '*prevented us [CUNY] from making an objective assessment*' of the allegations of research misconduct" (Ex. 162 at 1 (emphasis in original) (quoting CUNY report)).

6. Federal Indictment of Dr. Wang for Fraud

On June 28, 2024, the DOJ announced that "a federal grand jury in the District of Maryland returned an indictment yesterday charging [Dr. Wang] for defrauding the U.S. National Institutes of Health (NIH) of approximately \$16 million in federal grant funds." ¹⁸

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¹⁶ The Court may take judicial notice of relevant media coverage in considering the broader context in which allegedly defamatory statements were made. *See Condit v. Dunne*, 317 F. Supp. 2d 344, 357 (S.D.N.Y. 2004)

¹⁷ See, e.g., Apoorva Mandavilli, "Scientists Question Data Behind an Experimental Alzheimer's Drug," *The New York Times* (Apr. 18, 2022), https://www.nytimes.com/2022/04/18/health/alzheimers-cassava-simufilam.html

¹⁸ U.S. Department of Justice, Press Release (June 28, 2024), "Professor Charged for Operating Multimillion-Dollar Grant Fraud Scheme," https://www.justice.gov/opa/pr/professor-charged-operating-multimillion-dollar-grant-fraud-scheme

The DOJ press release recognized Dr. Wang's role as "a paid advisor and consultant to a publicly traded Texas biopharmaceutical company," and disclosed the following:

From approximately May 2015 through approximately April 2023, Wang allegedly engaged in a scheme to fabricate and falsify scientific data in grant applications made to the NIH on behalf of himself and the biopharmaceutical company. As alleged, the fraudulent grant applications to the NIH sought funding for scientific research of a potential treatment and diagnostic test for Alzheimer's disease and resulted in the award of approximately \$16 million in grants from approximately 2017 to 2021, part of which funded Wang's laboratory work and salary.

The indictment alleges that Wang's work under these grants was related to the early developmental phases of the proposed drug and diagnostic test, typically referred to by the U.S. Food and Drug Administration as Phase 1 and Phase 2. Wang's alleged scientific data falsification in the NIH grant applications related to how the proposed drug and diagnostic test were intended to work and the improvement of certain indicators associated with Alzheimer's disease after treatment with the proposed drug.

Wang is charged with one count of major fraud against the United States, two counts of wire fraud, and one count of false statements.

(Id. (emphasis added).)19

The criminal charges of "data falsification" against Dr. Wang concern the same data underlying simufilam that the Dot.com Defendants have focused on in their critiques.²⁰

C. Dot.com Defendants' FDA Letter, Slide Decks, and Tweets

It is within this broader context that the Dot.com Defendants published their critiques of Cassava and simufilam on their website, "cassavafraud.com," and Twitter. (See SAC ¶¶ 14-18, 135-136, 207, 234, 256, 652; see also Exs. 11, 19, 24, and 34.)

¹⁹ See Indictment, *United States v. Wang*, Case No. 24-cr-00211-TDC (D. Md.), Dkt. 1. Judicial notice may be taken of public records, including "arrest reports, criminal complaints, indictments, and criminal disposition data." *Awelewa v. New York City*, 2012 WL 601119, at *2 (S.D.N.Y. Feb. 23, 2012).

²⁰ Dot.com Defendants expressly reserve all available defenses and grounds for dismissing the SAC arising from or related to this indictment, announced the same date this motion was due, including the right to further address the significance of the indictment on reply.

First, on November 2, 2021, the Dot.com Defendants sent a letter to the FDA to express "grave concerns regarding Cassava" based on "an assessment" of its simufilam studies "made available for public scrutiny." (FDA Letter at 2.)²¹ The FDA Letter stated that the Dot.com Defendants "support the allegations made" in the Citizen Petition (id.); described the "methods by which, we allege, Cassava Sciences has either obfuscated or fabricated data during" clinical trials (id.); stated that "there is a material concern regarding the sponsor's credibility and very real risk of exposing thousands of patients to a compound with unknown risk" (id.); and provided a list of "questions that should be answered before trials continue" (id. at 5). The FDA Letter concluded that "[g]iven the obfuscation of clinical benefit outlined in this document . . . there is no justification for large-scale exposure to this drug" (id. at 23), "only the conduct of a full, thorough investigation of the data, investigators, sponsor, and collaborators can provide reassurance" (id. at 24), and asked that the simufilam program "be reviewed" by the FDA (id.). See also Cassava, 2024 WL 1347362, at *3 (describing FDA Letter).)

Second, on November 3, 2021, the day after sending the letter to the FDA, the Dot.com Defendants published a slide deck entitled "Cassava Sciences: A Shambolic Charade" (the "Shambolic Charade Deck"). In the Shambolic Charade Deck, the Dot.com Defendants noted that they held "stock and options positions that may benefit from a decline in Cassava Sciences' stock price" (id. at 3); and explained that their "analysis is entirely based on publicly available information and visible for everyone to see and challenge" (id. at 4). As summarized on the Deck's overview slide (id. at 6), it repeated the "key issues and questions" raised in the FDA Letter (id.); described "Cassava's suspicious history and the obvious scientific misconduct

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²¹ Cassava previously submitted the Dot.com Defendants' publications with the FAC, including the FDA Letter (Dkt. 30-8), Shambolic Charade Deck (Dkt. 30-9), and SavaDX Deck (Dkt. 30-12). Although Cassava did not resubmit these three documents, they are integral to and incorporated by reference into the SAC. (*See, e.g.,* SAC ¶¶ 14-18, 135-136, 207, 234, 256, 652; *see also* Exs. 11, 19, 24, and 34.).

pervading all of Cassava's preclinical science" (*id.*); presented "the egregious data anomalies and manipulation of both the biomarker and cognitive measurements from Cassava's Phase 2 trials" (*id.*); presented an "honest account of what Cassava did, and theory of why they did so" (*id.*)—described on a slide titled "[o]ur version of events" (*id.* at 35); and, finally, repeated the assertion that "only the conduct of a full, thorough investigation of the data, investigators, sponsor, and collaborators can provide reassurance" (*id.* at 36). *See also Cassava*, 2024 WL 1347362, at *3 (describing Shambolic Charade Deck). ²²

Third, on November 29, 2021, the Dot.com Defendants posted a slide deck entitled "SavaDx Exposed" (the "SavaDX Deck"). The Deck examined "SavaDx", Cassava's "investigational diagnostic to detect Alzheimer's disease" (id., at 3) with the subtitle: "a revolutionary diagnostic for Alzheimer's Disease or a scam of scientifically illiterate investors?" (id. at 2). The Deck questioned the research underlying SavaDx (id. at 5-8) and summarized data and email correspondence the Dot.com Defendants had obtained through public records requests (id. at 9-16). The Deck also included links to websites containing the cited materials. (Id. at 17, 28.) See also Cassava, 2024 WL 1347362, at *4 (describing SavaDX Deck).

Fourth, in December 2021, the Dot.com Defendants posted a report entitled "Cassava and the Wang Lab: Seeing Through the Blind." (SAC ¶¶ 255-259, Ex. 28 (the "Seeing Through the Blind Deck"). The Deck raised concerns about Cassava and Dr. Wang based on additional email correspondence obtained through public records requests. (Id. at 9.) Specifically, the Seeing Through the Blind Deck stated that "[b]ased on the obtained emails" the Dot.com

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²² On or around November 3, 2021, Defendant QCM also published a report, titled "Cassava Sciences (SAVA): Game Over! A warning for the US healthcare system" (*see* Dkt. 30-10; *see also* SAC ¶ 143), expressing similar concerns and opinions as the Neuroscientist Defendants and Dot.com Defendants. *See Cassava*, 2024 WL 1347362, at *4 (describing QCM Report). Like the Dot.com Defendants, QCM also published its report and opinions on Twitter (*see* Dkt. 30-2). *See also Cassava*, 2024 WL 1347362, at Exhibit A.

Defendants "conclude" there is "a risk of biomarker data manipulation" and "previous assurances of data integrity are suspect." (*Id.*) Again, the Seeing Through the Blind Deck included images and links to websites containing the cited materials. (*Id.*) *See also Cassava*, 2024 WL 1347362, at *4 (describing Seeing Through the Blind Deck).

In connection with their websites, FDA Letter, and Slide Decks, the Dot.com Defendants actively participated in debates on Twitter (renamed X in July 2023) among critics and defenders of Cassava, including Cassava investors, other scientists, and other short sellers. ²³ This community on Twitter uses the hashtag \$SAVA when posting commentary about Cassava or simufilam, conveying that such Tweets are part of a long-running debate over the legitimacy of simufilam's underlying science, the value of Cassava's stock, and allegations of scientific fraud against Cassava. (*See* SAC ¶ 134.) The \$SAVA hashtag hyperlinks to all other posts on the platform that mention it. *See United States v. Mackey*, 652 F. Supp. 3d 309, 320 (E.D.N.Y. 2023) ("The court notes that on Twitter . . . hashtags also serve as a link between different posts that have used the same hashtag"). Indeed, all of the challenged Twitter threads use the \$SAVA hashtag/link. (*See, e.g.*, Ex. 6 (Statement 1).)

Regular participants in these \$SAVA debates include the Dot.com Defendants, other scientists, other short sellers (*e.g.*, QCM), and Cassava investors, who, based on their regular use of the \$SAVA hashtag are generally known and easily recognizable as critics or defenders of Cassava. For example, Dr. Heilbut's Twitter profile links to a website (logphase.com) that directs users to cassavafraud.com, where the FDA Letter and Slide Decks are prominently featured. The Dot.com Defendants repeatedly "post[ed] links" on Twitter to cassavafraud.com,

²³ The Dot.com Defendants' Twitter profiles or handles are available at the following links: Dr. Heilbut (<u>@Adrian H</u>); Dr. Brodkin (<u>@jesse brodkin</u>); and Dr. Milioris (<u>@DRnotaDR</u>).

which, in turn, were "reposted and shared extensively" on the platform. (SAC ¶ 652; see also, id. ¶¶ 132-135, Exs. 11, 19, 24, 34.) 24

As a result, the Dot.com Defendants are well-known on Twitter for their conclusion that Cassava and Dr. Wang manipulated or fabricated the research and laboratory data underlying simufilam's purported mechanism and effects, while Cassava's defenders frequently respond by dismissing such criticism and attacking the Dot.com Defendants based on their short positions (see, e.g., Exs. 7, 21, 40, 60, 62, 63, 65).

D. Procedural History

On November 2, 2022, Cassava commenced this defamation action, asserting claims against the Dot.Com Defendants, Neuroscientist Defendants, and Quintessential Capital Management, LLC ("QCM"). (Dkt. 1.) On November 4, 2022, Cassava filed its First Amended Complaint against all seven Defendants (Dkt. 30, "FAC"), attaching and incorporating 106 exhibits (many of which contain multiple links) spanning nearly 1,600 pages.

1. The Court's Decision to Grant Defendants' Motions to Dismiss the FAC

Between January and March 2023, the Dot.Com Defendants, Neuroscientist Defendants, and QCM each filed a motion to dismiss the FAC (see Dkts. 74, 77, 78, 86, and 87). In January 2024, Magistrate Judge Wang issued three reports recommending that the motions be granted in their entirety. (See Dkts. 104, 105, 110.) Cassava filed objections to all three reports (Dkts. 108, 109, 115), and each group of Defendants filed responses (112, 113, 116).

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²⁴ The Court may take judicial notice of the fact that the Dot.com Defendants posted links to cassavafraud.com on

Twitter dozens of times over the same period as the allegedly defamatory statements, spanning from November 2021 to March 2024 (see, e.g., Dr. Heilbut's Tweet, Dr. Brodkin's Tweet, Dr. Milioris's Tweet). See Carter v. Scripps Networks, LLC, 670 F. Supp. 3d 90, 98 (S.D.N.Y. 2023) (taking judicial notice of website, its "links to third-party" products, and disclosures that it "may make money from these affiliate links"); Hesse v. Godiva Chocolatier, Inc., 463 F. Supp. 3d 453, 463 (S.D.N.Y. 2020) ("[A] court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute.").

On March 28, 2024, Judge Woods issued his decision granting Defendants' motions to dismiss the FAC. *See Cassava Scis., Inc. v. Bredt*, No. 1:22-CV-9409-GHW, 2024 WL 1347362 (S.D.N.Y. Mar. 28, 2024). Judge Woods determined that certain of the challenged Tweets, "examined . . . in isolation" could be actionable as statements of fact with a defamatory meaning, *id.* at *21 n.42, but that the FAC nevertheless failed to state a claim because it did not allege facts sufficient to show actual malice, *see id.* at *22-28.

In Exhibit A to his opinion, Judge Woods provided a list of Tweets that he found to be defamatory statements of fact "based on the limited allegations before [the Court]," but Judge Woods "emphasize[d] that contextual allegations, such as allegations about the thread in which a challenged tweet was posted, allegations about other tweets that the author posted in close proximity to a challenged tweet, or allegations about the author's X profile *might impact each of those determinations*." *Id.* at *21 n.42 (emphasis added).

Finally, Judge Woods stated:

[T]he Court cannot conclude that amendment of the Complaint to replead Plaintiff's claims with respect to the challenged tweets would be futile. Plaintiff challenged hundreds of tweets but provided few individualized allegations regarding the context of each tweet. Additionally, the Court cannot conclude that it would be futile for Plaintiff to replead its allegations of actual malice with respect to the challenged tweets and the challenged statements in the Seeing through the Blind Deck regarding the Open Label Study.

Id. at *29. Accordingly, Judge Woods granted Cassava partial leave to file a second amended complaint with respect to "these deficiencies." *Id.*

2. Cassava's Second Amended Complaint

On April 29, 2024, Cassava filed the SAC (Dkt. 120), including an index (Dkt. 120-1), Appendix A (Dkt. 120-2),²⁵ and 192 exhibits (Dkts. 121-1 to 126-32) that span 1,929 pages.

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²⁵ Cassava's Appendix A appears to omit content on pages 6 and 7.

The SAC asserts claims for defamation (*see* Counts 1-4, SAC ¶¶ 667-726) and conspiracy to defame (*see* Count 5, SAC ¶¶ 727-732) against each of the Dot.com Defendants, based on 75 allegedly defamatory statements, including 74 statements on Twitter (*see* Statements 1-22, Exs. 6-27; Statements 24-75, Exs. 29-80) and one statement in the Seeing Through the Blind Deck (*see* Statement 23, Ex. 28). The "overall message" of the challenged statements "was that Cassava engaged in fraudulent and illegal activity by, among other things, fabricating test results and lying to government agencies and investors." (SAC ¶ 7.)

Ten of the 75 challenged statements were not alleged in the FAC and thus not on the list of statements for which the Court granted Cassava leave to amend. *Compare* Statements 50, 55, 66, and 68-75, *with Cassava*, 2024 WL 1347362, Exhibit A. These 10 new statements include four that pre-date the FAC (Statements 50, 55, 66, and 68) and six that post-date the FAC (Statements 69-75).²⁶

Aside from the 75 Exhibits containing the challenged statements, Cassava resubmitted Exhibits previously attached to the FAC and 36 additional Exhibits described below:

- Two Cassava Form 10-K SEC filings from 2023 and 2024 (Exs. 82-83);
- Twenty-seven Cassava press releases issued between November 2022 and March 2024 (Exs. 143-169);
- Three articles or abstracts by Dr. Wang or Dr. Burns from May, June, and September 2023 (Exs. 4, 5, 191); and
- Four articles by other scientists published between May 2022 and February 2023 (Exs. 186-189).

Finally, the Exhibits of the challenged statements still contain only partial images of the threads in which the challenged Tweets were made—not the entire threads. The full threads are

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²⁶ Statements 55, 66, and 68 appear to come from the same threads as three statements in Exhibit A to the Court's decision, but Cassava now seeks to challenge a different statement in each thread.

available at the links on the first page of each Exhibit and in the Dot.com Defendants' **Appendix**1 submitted herewith.

ARGUMENT

I. <u>LEGAL STANDARDS</u>

A. Rule 12(b)(6) Standard

To survive a motion to dismiss under Rule 12(b)(6), a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). The Court must draw all reasonable inferences in favor of plaintiff; however, "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*.

A court must generally "limit itself to the facts stated in the complaint." *Field Day, LLC v. Cnty. of Suffolk*, 463 F.3d 167, 192 (2d Cir. 2006) (quoting *Hayden v. Cnty. of Nassau*, 180 F.3d 42, 54 (2d Cir. 1999)). A court may also consider "documents attached to the complaint as exhibits, . . . documents incorporated by reference in the complaint . . . [and] document[s] integral to the complaint." *DiFolco v. MSNBC Cable L.L.C.*, 622 F.3d 104, 111 (2d Cir. 2010) (internal citations omitted). A court may consider these documents "not to prove the truth of their contents but only to determine what the documents stated." *Glob. Network Comme'ns, Inc. v. City of New York*, 458 F.3d 150, 157 (2d Cir. 2006) (quoting *Kramer v. Time Warner Inc.*, 937 F.2d 767, 774 (2d Cir. 1991)); *see also Cassava*, 2024 WL 1347362, at *6.

B. Defamation Standard

To state a claim for defamation, "a complaint must allege '(1) a false statement that is (2) published to a third party (3) without privilege or authorization, and that (4) causes harm, unless the statement is one of the types of publications actionable regardless of harm." *Elias v. Rolling*

Stone LLC, 872 F.3d 97, 104 (2d Cir. 2017) (quoting Stepanov v. Dow Jones & Co., 987 N.Y.S.2d 37, 41 (1st Dep't 2014)). In addition, when a defamation claim is brought by a public figure, "the First Amendment independently requires a showing that the defendant acted with 'actual malice." N.Y. Times Co. v. Sullivan, 376 U.S. 254, 279–280 (1964); Cassava, 2024 WL 1347362, at *6. Likewise, under New York law, "[i]f an alleged defamatory statement relates to 'any communication in a place open to the public or a public forum in connection with an issue of public interest,' then a plaintiff must plead 'actual malice' pursuant to New York's anti-SLAPP statute." Puentes v. Union Coll., No. 12-cv-373-LEK-DJS, 2024 WL 1328914, at *9 (N.D.N.Y. Mar. 28, 2024) (quoting N.Y. Civ. Rights Law § 76-a); see also Acosta v. Vann, No. 614173/2023, 83 Misc. 3d 1217(A), 2024 WL 3035174 (N.Y. Sup. Ct. June 17, 2024).

On a motion to dismiss, the court "must decide whether the statements, considered in the context of the entire publication, are reasonably susceptible of a defamatory connotation, such that the issue is worthy of submission to a jury." *Stepanov*, 987 N.Y.S.2d at 42 (internal quotations omitted). That determination is "guided not only by the meaning of the words as they would be commonly understood . . . but by the words considered in the context of their publication." *Levin v. McPhee*, 119 F.3d 189, 195 (2d Cir. 1997) (citing *Armstrong v. Simon & Schuster, Inc.*, 85 N.Y.2d 373, 381 (1995)). Challenged statements must not "be read in isolation, but must be perused as the average reader would against the whole apparent scope and intent of the writing." *Celle v. Filipino Rep. Enters. Inc.*, 209 F.3d 163, 177 (2d Cir. 2000) (internal citations omitted); *see also Cassava*, 2024 WL 1347362, at *7.

II. CASSAVA DOES NOT AND CANNOT PLEAD FALSITY

Falsity is an essential element of defamation. *See Tannerite Sports, LLC v.*NBCUniversal News Grp., 864 F.3d 236, 247 (2d Cir. 2017). Accordingly, a plaintiff must plead

facts sufficient to "establish that the defendant's statements were not substantially true." *Id.* "Whether a statement is substantially true is an issue of law properly decided on a motion to dismiss, provided that the Court limits its consideration to materials appropriately considered on such a motion." *Nunes v. NBCUniversal Media, LLC*, 643 F. Supp. 3d 403, 413 (S.D.N.Y. 2022).

Here, the crux of Cassava's claim is that the Dot.com Defendants defamed Cassava by accusing the company of relying on manipulated or fabricated data and by asserting or implying that Cassava was therefore a "fraud." (*See, e.g.,* SAC ¶ 7.) For example, the SAC emphasizes the allegedly defamatory "tag line" used in many of the challenged Tweets: "it's all made up." (*See* SAC ¶ 133.) To plead "falsity," Cassava asserts that it "can prove" the alleged data fabrication or manipulation "did not happen." (*See, e.g.,* SAC ¶¶ 646-646.) These conclusory assertions fail for two reasons.

First, the SAC does not (and cannot) plead that Cassava has the original, raw data necessary to refute accusations of data manipulation or fabrication. In fact, Cassava's pleadings indicate that neither Cassava nor Dr. Wang has preserved any original data. In September 2021, Cassava's CEO admitted that "one way to settle the discourse" around data manipulation is "to go back to the original films and images," but Cassava "[does not] have the original films or images for the Western blots in question." (Sept. 3, 2021 Tr. at 5.) For that reason, Cassava asked CUNY to investigate and release its findings to the public. (Id.) However, as reported by Cassava in October 2023, Dr. Wang's "internal recordkeeping failures" "prevented" CUNY "from making an objective assessment" of the allegations of data manipulation or fabrication. (Ex. 162 at 1.) Similarly, the Editor's Note and FDA inspection report further confirm that Dr.

Wang had no records from his "re-do" analysis of simufilam's phase 2b trial.²⁷ In the absence of original data, Cassava cannot refute the purported accusations that "it's all made up," at the heart of its defamation claims and thus cannot plead (let alone ever prove) "falsity."

Second, Cassava cannot plead around the fact that simufilam's foundational research is contested and unreliable. Most notably, the retraction of Dr. Wang's 2008 PLoS One article and the errors conceded by Drs. Burns and Wang in their 2017 Neurobiology of Aging article mean that Cassava's "foundational" and patented claim that simufilam can bind filamin A is unsupported. Likewise, the only independent analysis of simufilam's Phase 2b trials indicated that the drug did not work, and it was only upon Dr. Wang's "re-do" analysis (based on records that no longer exist) that Cassava touted the trial "results" as positive. Finally, even Cassava's CEO admitted to errors in simufilam's underlying research, describing them as "visual errors" and "honest" mistakes, rather than signs of fraud. (See, e.g., Sept. 3, 2021 Tr. at 8.)

In sum, on the facts alleged, Cassava cannot refute the central premise of the challenged statements. That is, the "foundational" research underlying simufilam contains signs of data manipulation or fabrication; Cassava does not and cannot plead that original data exists to prove otherwise; and the federal indictment of Dr. Wang for falsifying such data is perhaps the clearest sign yet that the Dot.com Defendants have been right all along. The defamation claims fail for this reason alone. *See Eros Int'l. PLC v. Mangrove Partners*, No. 653096/2017, 2019 WL 1129196, at *8 (N.Y. Sup. Ct. Mar. 8, 2019) (dismissing claims where plaintiff could "not

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²⁷ Cassava cannot rely on its own failure to submit or mention the Editor's Note or FDA inspection report, when it has pleaded extensive details about the phase 2b study and relied on the study's "re-do" results as foundational support for simufilam (*see* SAC ¶¶ 62-78, 137, 239, 537, 556.e, 556.i, 556.o, 556.r-t, 556.pp, 608). *See Ginx, Inc. v. Soho All.*, 720 F. Supp. 2d 342, 352 (S.D.N.Y. 2010) ("Plaintiffs' failure to include matters of which as pleaders they had notice and which were integral to their claim—and that they apparently most wanted to avoid—may not serve as a means of forestalling the district court's decision on the motion.") (quoting *Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 44 (2d Cir. 1991)).

dispute the underlying facts" or "the existence of the source material"); see also Croce v. Sanders, 843 F. App'x 710, 717 (6th Cir. 2021) (relying on corrections in scientific journals in finding underlying accusation "that people in [plaintiff's] lab have violated scientific norms" to be "substantially true").

III. CASSAVA DOES NOT AND CANNOT PLEAD ACTUAL MALICE

As this Court already found, Cassava "is a limited purpose public figure with respect to simufilam research and therefore is required to plead actual malice." *Cassava*, 2024 WL 1347362, at *22. Indeed, under New York's anti-SLAPP statute, actual malice is required to challenge statements on public fora, such as Twitter, concerning issues of "public interest," such as Alzheimer's research. N.Y. Civ. Rights Law § 76-a-1(a)-(d) (defining "public interest" "broadly" as any subject "other than a purely private matter"); *see Aristocrat Plastic Surgery*, *P.C. v. Silva*, 206 A.D.3d 26, 30 (1st Dep't 2022) (noting "expansive interpretation" of "public interest" under Section 76-a-1(d)); *Goldman v. Reddington*, No. 18-cv-3662, 2021 WL 4099462, at *4 (E.D.N.Y. Sept. 9, 2021) (recognizing Twitter as a public forum under § 76).

Accordingly, Cassava must plead that each allegedly defamatory statement was made "with knowledge that it was false or with reckless disregard of whether it was false or not." *Church of Scientology*, 238 F.3d at 173-174 (quoting *Sullivan*, 376 U.S. at 280)); N.Y. Civ. Rights Law § 76-a(2). "If it cannot be shown that the defendant knew that the statements were false, a plaintiff must demonstrate that the defendant made the statements with reckless disregard of whether they were true or false." *Church of Scientology*, 238 F.3d at 174. "The reckless conduct needed to show actual malice 'is not measured by whether a reasonably prudent man would have published, or would have investigated before publishing,' but by whether there is sufficient evidence 'to permit the conclusion that the defendant *in fact entertained serious*

doubts as to the truth of his publication." *Id.* (quoting *St. Amant v. Thompson*, 390 U.S. 727, 731 (1968) (emphasis added)).

"Although actual malice is subjective, a 'court typically will infer actual malice from objective facts." *Celle*, 209 F.3d at 183 (quoting *Bose Corp.*, 692 F.2d at 196)). "These facts should provide evidence of 'negligence, motive and intent such that an *accumulation of the evidence and appropriate inferences* supports the existence of actual malice." *Id.* (emphasis in original). Moreover, the Supreme Court deemed the following factors relevant to a showing of actual malice:

(1) whether a story is fabricated or is based wholly on an unverified, anonymous source, (2) whether the defendant's allegations are so inherently improbable that only a reckless person would have put them in circulation, or (3) whether there are obvious reasons to doubt the veracity of the informant or the accuracy of his reports.

Id. (citing Amant, 390 U.S. at 732); see also Cassava, 2024 WL 1347362, at *24.

A. <u>Cassava Recycles the Same Actual Malice Allegations that the Court Already</u> Found Insufficient and "Unpersuasive"

The SAC's assertions of actual malice are nearly identical to those alleged in the FAC and fail for the same reasons. (See SAC, Section VII, ¶¶ 544-621; see also ¶ 142 (passim).) As this Court already found, Cassava's "various assertions" of actual malice go to either the second Amant factor (i.e., statements so "inherently improbable" only a reckless person would publish them) or the third Amant factor (i.e., statements published despite obvious reasons to doubt their veracity). Cassava, 2024 WL 1347362, at *24. In particular, the Court previously considered and found "unpersuasive" Cassava's assertions:

(1) that Defendants and their sources were biased against Plaintiff or had a motive to defame Plaintiff, (2) that Defendants did not meet with Plaintiff or certain other knowledgeable people to investigate their concerns before publishing their statements, (3) that Defendants had access to 'contradictory information' when they published their statements, (4) that 'common knowledge in the scientific community' contradicted Defendants' beliefs, and (5) that other circumstances, including Plaintiffs' receipt of grants, publications of its research in peer-reviewed

journals, and approval from regulators made Defendants' statements 'inherently improbable.'

Cassava, 2024 WL 1347362, at *24; see also id. at *24 n.43-44.

In the SAC, Cassava repeats—and merely rearranges—most of these same assertions without pleading any new facts "to permit the conclusion" that the Dot.com Defendants "entertained serious doubts as to the truth" of their statements. *Church of Scientology*, 238 F.3d at 174. Moreover, in a futile attempt to plead facts specific to each of the challenged statements, the SAC merely repeats *ad nauseum* the same or substantially same boilerplate assertions of actual malice 75 times (*see, e.g.,* SAC ¶¶ 142, 152, 169, 180, 185, 190, 201, 206, 211, 216, 221, etc.) Thus, once again, "[t]aken together, Plaintiff's copious allegations fail to rise to the 'accumulation of the evidence and appropriate inferences' necessary to adequately plead actual malice." *Cassava*, 2024 WL 1347362, at *24 (quoting *Celle*, 209 F.3d at 183).²⁸

1. Motive and Bias

The SAC repeats the FAC's assertions that the Dot.com Defendants' short positions provided an "improper motive" that supports an inference of actual malice. (Compare FAC ¶¶ 290-294, with SAC ¶¶ 619-621.) These allegations fail for the same reasons as before. See Cassava, 2024 WL 1347362, at *25. Indeed, as the Court recognized, the Dot.com Defendants' short positions do not indicate actual malice, but rather, could "support the contrary inference" of "genuine conviction that Plaintiff's stock was overvalued." Id. "After all, by shorting the stock," the Dot.com Defendants "put their money behind their belief." Id. At most, the Dot.com Defendants' short positions "plausibly created a profit motive to publicize [their] critiques," but "that does not lead the Court to infer" that they "did not subjectively believe those critiques." Id.

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²⁸ Indeed, the indictment of Dr. Wang, which contains substantially similar allegations as those articulated by the Dot.com Defendants, renders Cassava's entire theory of actual malice implausible on its face.

(citing *Biro v. Condé Nast*, 963 F. Supp. 2d 255, 278 (S.D.N.Y. 2013) ("[T]he operative question is whether a defendant failed to investigate in the face of actual, *subjective* doubts.") (emphasis added). Thus, the SAC's "motive" allegations "do not suffice to support an inference of actual malice." *Id.* at *25.

2. Failure to Investigate

Cassava has abandoned its prior allegations that Defendants "purposefully avoided" the truth by declining to raise their concerns with Cassava's board, executives, scientists, or employees before airing them publicly. *See Cassava*, 2024 WL 1347362, at *25 (addressing FAC ¶¶ 331-346).) In fact, as with the FAC, the SAC and "the documents incorporated" therein "describe the intensive investigations" that the Dot.com Defendants "undertook to develop" their FDA Letter and Slide Decks, "which describe the bases for the beliefs expressed in the challenged tweets" and "contain extensive research." *Id.* Although Cassava has abandoned its prior allegations based on a "failure to investigate" and "purposeful avoidance," Cassava cannot escape the reality, evident from their pleadings, that the Dot.com Defendants conducted extensive investigations and research to support their statements. This undercuts all of Cassava's scattershot and fact-free assertions of actual malice. *See Church of Scientology*, 238 F.3d at 174 (finding that a defendant's extensive investigation cut against a finding of actual malice).

3. Contradictory Information

As the Court already determined, Cassava's "allegations that Defendants had access to information that 'contradicted' the challenged tweets or the sources on which those challenged tweets were based [] do not support an inference of actual malice." *Cassava*, 2024 WL 1347362, at *26. Cassava nevertheless repeats these same assertions in the SAC. (*See* SAC ¶¶ 550-559). Specifically, the SAC recycles the FAC's conclusory allegations (in many cases, carbon copied) that the Dot.com Defendants had access to "contradictory" information in:

- Cassava's SEC filings (*compare* FAC ¶¶ 303-304, Exs. 20-22, *with* SAC ¶¶ 552-554, Exs. 84-86);
- Cassava's press releases (*compare* FAC ¶¶ 305-307, Exs. 16-18, 23-76, *with* SAC ¶¶ 555-557, Exs. 87-142);
- Journal articles by Dr. Wang, Dr. Burns, and other scientists discussing the "foundational" science relied on by Cassava to develop simufilam (*compare* FAC ¶¶ 308-312, Exs. 77-92, *with* SAC ¶¶ 558-562, Exs. 82-92, 170-173, 192); and
- "[E]valuations conducted by science journals" that allegedly "found no evidence that Cassava fabricated, manipulated, or doctored results" (*compare* FAC ¶ 361, Exs. 16-19, *with* SAC ¶¶ 564-565, Exs. 81, 133, 141, 190).

As this Court previously found, none of this supposedly "contradictory" information can support a finding of actual malice. *See Cassava*, 2024 WL 1347362, at *26.

First, with respect to "contradictory" information in Cassava's SEC filings and press releases—Judge Woods found that Cassava's "[d]enials are of especially limited value in this case, given that Defendants expressed concerns that Plaintiff may be engaging in a years-long pattern of coordinated dishonesty." Id. (citing Edwards v. Nat'l Audubon Soc'y, 556 F.2d 113, 121 (2d Cir. 1977); Baiul v. Disson, 607 F. App'x 18, 21 (2d Cir. 2015)). The same reasoning defeats the SAC's substantially similar assertions. (See SAC ¶¶ 552-554, Exs. 84-86; SAC ¶¶ 555-557, Exs. 87-142.)

Second, with respect to the "contradictory" articles by Dr. Wang, Dr. Burns, and other scientists resubmitted again with the SAC—the Court already recognized that "only one of the studies . . . tested simufilam," and "many did not draw conclusions about Alzheimer's, filamin A, or either one." Cassava, 2024 WL 1347362, at *26. For example, the SAC again relies on a Yale study published in February 2020 (Exs. 3, 183), claiming that it is an "independent" and "confirmatory study relating to simufilam" (SAC ¶¶ 113-114) that supports the "foundational science for simufilam as a potential treatment for Alzheimer's disease" (id. ¶ 561-j; see also id. ¶¶ 115, 488-489, 494, 607). However, the Court already reviewed this study and "could not

determine that any of the conclusions of the study contradicted Defendants' claims," noting that the study "found that inhibiting filamin A reduced seizure activity in mice, not that simufilam or inhibition of filamin A was effective at treating Alzheimer's in humans." *Cassava*, 2024 WL 1347362, at *25 n. 45. The Court further recognized that Cassava's "Dr. Burns is listed as an author on the allegedly 'independent' study." *Id*.

Once again, Cassava fails to "allege that the conclusions of those articles directly conflicted with any of the inferences or opinions contained in tweets" or the Seeing Through the Blind Deck. Cassava, 2024 WL 1347362, at *26. Instead, the SAC merely asserts that these journal articles provided simufilam's "foundational science"; "confirmed the potential effectiveness of simufilam"; and "implicate filamin protein in disease." (SAC ¶ 558-562.) These propositions are so generic and so remote from the questions that bear upon simufilam's ostensible mechanism of action as to be laughable. Certainly, it falls far short of pleading a direct conflict with the Dot.com Defendants' statements, which arise "specifically" from "anomalous methodologies and results in Plaintiff's, Dr. Wang's, and Dr. Burns' studies" and bear upon the specific questions whether simufilam binds with filamin A and whether it does so in a manner that alters the conformation or function of that or any other proteins in the brain. *Id.* The gist of the allegations here is that the Dot.com Defendants examined the anomalies in Cassava's and Dr. Wang's scientific method and posited that Cassava's claims about simufilam, including specifically its supposed link to filamin A, were "made up." *Id.* None of these studies directly refutes anything about the challenged statements. Hence, they cannot support an inference of actual malice.

Third, Cassava repeats its assertion that the scientific journals, which investigated concerns over data manipulation in studies by Dr. Burns and Dr. Wang, "found no evidence that

Cassava fabricated, manipulated, or doctored results." (SAC ¶ 564-565.) However, none of the "evaluations" can be credibly construed as offering anything close to an exoneration of Dr. Wang, Dr. Burns, or Cassava. For example, the SAC refers to the *Journal of Neuroscience*, which initially reported that "[n]o evidence of data manipulation was found," (SAC ¶ 564.a); however, the journal then issued a follow-up "Expression of Concern" regarding the same article, due to unresolved "concerns about Western blots . . . including those published with the article's erratum," and stating that it "will await the outcome of [CUNY's] investigation before taking further action."²⁹ Nor does Cassava address any of the retractions of Dr. Burns's or Dr. Wang's research, such as the March 2022 retraction by *PLoS One* of the 2008 article that contained the research underlying Cassava's patent for simufilam and the foundational claim that naloxone and simufilam could bind filamin A. (See FDA Letter at 2-3 (disputing 2008 paper and explaining its foundational role in simufilam's development); see also Statement 59 (discussing and providing screenshot of retraction).) In any event, even if any journal had affirmatively rejected allegations of data manipulation or offered anything close to an exoneration (and none did)—that still would not support a finding of actual malice, because, as this Court recognized, "scientific fraud that dupes . . . academic journals is, sadly, not unheard of." Cassava, 2024 WL 1347362, at *28.

Finally, Cassava asserts 34 "contradictory" facts purportedly derived from these same "contradictory" sources recycled from the FAC (id. ¶¶ 570-604). Once again, however, Cassava fails to identify which purported "fact" comes from which "source." The supposed "Facts" concern simufilam's (unsupported) link to filamin A and impact on brain health (see "Facts" 1-

²⁹ *JNeurosci*, "Expression of Concern: Wang et al., 'Reducing Amyloid-Related Alzheimer's Disease Pathogenesis by a Small Molecule Targeting Filamin A' [2012]" (Jan. 19, 2022), https://doi.org/10.1523/JNEUROSCI.2306-21.2021

6); the general regulatory process for studies of experimental drugs (*see* "Facts" 7-13); Cassava's participation in that regulatory process to develop simufilam (*see* "Facts" 14-28); and Cassava's responses to criticism regarding errors and anomalies in simufilam's foundational research (*see* "Facts" 29-34). These purported "Facts" merely recite the bases for Cassava's "disagreements with the Defendants' scientific inferences and opinions." *Cassava*, 2024 WL 1347362, at *12. Indeed, most of the "Facts" are general assertions, while many others merely describe historical events in simufilam's development. Cassava does not even attempt to connect the dots, as it must, by alleging how and why these general "Facts" directly refute any particular statement by the Dot.com Defendants (and they do not). (*See also infra* Section III.C.) Thus, they cannot support a finding of actual malice. *See Cassava*, 2024 WL 1347362, at *27 n.48.

4. Common Knowledge in the Scientific Community

Cassava repeats the FAC's allegations that the Dot.com Defendants' statements were "inconsistent with common knowledge" (compare FAC ¶¶ 316-330, with SAC ¶¶ 613-615). The "crux" of Cassava's "common knowledge" theory, once again, "is that Defendants knew that many of the alleged anomalies that they observed did not necessarily indicate data manipulation or errors." Cassava, 2024 WL 1347362, at *27. These assertions fail for the same reasons they failed in the FAC. At most, they show that the Dot.com Defendants "were aware of alternative explanations" (besides fraud) to explain the anomalous and error-ridden data underlying simufilam. Id. But alternate possibilities do not support a finding of actual malice, particularly where, as is the case here, the Dot.com Defendants have based "their conclusions not on a single isolated anomaly, but on an alleged constellation of irregularities in results and suspect methodologies across many studies." Id.

5. Other Circumstances

The SAC repeats the FAC's claims that the Dot.com Defendants' statements were "inherently improbable" in light of Cassava's fundraising, research grants, survival of scrutiny by regulators, published scientific articles, and the conduct of its executives. (Compare FAC ¶¶ 347-356, with SAC ¶¶ 605-611.) These allegations fail for the same reasons as before. See Cassava, 2024 WL 1347362, at *28 ("Plaintiff alleges that Cassava raised hundreds of millions of dollars, won research grants, survived scrutiny by regulatory agencies, and published its studies in peer-reviewed journals. . . . But scientific fraud that dupes funders, regulatory agencies, and academic journals is, sadly, not unheard of."); see also Kesner v. Dow Jones & Co., Inc., No. 22-875, 2023 WL 4072929, at *3 (2d Cir. June 20, 2023) (finding that accusations were not inherently improbable "merely because others, including the SEC, had not directly accused [the plaintiff].").

Finally, Cassava repeats allegations from the FAC, claiming that Defendants "knew" they had no "firsthand evidence" to support their statements. (*Compare* FAC ¶¶ 296-299, *with* SAC ¶¶ 546-549.) Yet again, the Court already found these exact allegations to be "plainly contradicted" by the Dot.com Defendants' FDA Letter and Slide Decks (again incorporated into Cassava's pleadings), which show that "[t]he support for the allegedly defamatory tweets was the exhaustive research and analysis" fully disclosed in their FDA Letter and Slide Decks. *Cassava*, 2024 WL 1347362, at *24 n.44; *see also id.* at *25 (finding that the "bases for the beliefs expressed in the challenged tweets" were "the intensive investigations" and "extensive research" undertaken to develop the FDA Letter and Slide Decks).

B. Cassava's Supplemental Assertions of Actual Malice Fail

1. The "New" Allegations All Fail Because They Post-Date the Dot.com Defendants' Critiques

Cassava alleges no "new" facts that pre-date the Dot.com Defendants' initial critiques of Cassava and simufilam. Instead, the only additional facts alleged in the SAC to support "actual malice" come from 36 Exhibits that contain Cassava's own SEC filings (Exs. 82-83) and press releases (Exs. 143-169); three articles or presentations by Dr. Wang or Dr. Burns (Exs. 4, 5, 191); and four articles by other scientists (Exs. 186-189).

These supplemental assertions are of the same kinds as those previously asserted in the FAC—and thoroughly rejected by the Court. (*See supra* Section III.A.) In fact, they are even weaker than the assertions of "contradictory" information copied from the FAC, because all of the new sources (from May 2022 to March 2024) were published even *longer* after the Dot.com Defendants first "articulated their critiques of Plaintiff's work" (in 2021). *Cassava*, 2024 WL 1347362, at *26. Indeed, as the Court explained, "contrary statements" published "after Defendants articulated their critiques" can "do little to support an inference of actual malice." *Id.* The Court further recognized that even if Cassava could allege that the Dot.com Defendants were aware of some "contrary opinions" published *before* their initial critiques, such allegations would still be "insufficient" in this case, "given the number of Defendants" and other scientists and observers "who claimed to have come to the same conclusions." *Id.*³⁰

'serious doubts as to the truth of [their] publication[s]," their "repetition and republication" has "limited relevance to the Court's analysis of actual malice." *Cassava*, 2024 WL 1347362, at *24 n.44 (citing *Church of Scientology*, 238 F.3d at 174).

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³⁰ Likewise, the SAC rehashes the FAC's assertions that the Dot.com Defendants' "repetition and republication" of statements shows "actual malice." (*Compare* FAC ¶¶ 359-365, *with* SAC ¶¶ 616-618). The Court already rejected this theory, too—finding that because Cassava failed to plead that the Dot.com Defendants "had reason to entertain

Notably, these supposedly contradictory sources are easily outweighed by the DOJ's indictment of Dr. Wang for scientific fraud—adding the federal government to the chorus of critics who have reached the same conclusion as the Dot.com Defendants.

For these reasons, the Court can easily discard the SAC's "new" allegations and Exhibits purporting to show "actual malice," all of which concern supposedly "contrary statements" published months or years after the Dot.com Defendants articulated their critiques.

2. The "New" Sources Do Not Directly Contradict the Dot.com Defendants' Challenged Statements

Even if the Court were required to scour the additional 36 Exhibits for facts capable of supporting "actual malice" (and it is not), the Court would find nothing that confirms Cassava's contested claims about simufilam or refutes the Dot.com Defendants' statements.

Additional SEC Filings and Press Releases. Neither Cassava's SEC filings (SAC ¶¶ 553.a-b, Exs. 82-83), nor its 27 press releases (*id.* ¶¶ 556.fff-ffff, Exs. 143-169) provide any plausible support for a finding of actual malice. These partisan documents merely report financial results and subsequent events in simufilam's development. As the Court already recognized, Cassava's "publication of press releases and articles about results does not make Defendants' assertions inherently improbable," *Cassava*, 2024 WL 1347362, at *28, and Cassava's reliance on its own statements is "especially" unpersuasive here, considering the widely held belief that the company and Dr. Wang are "engaging in a years-long pattern of coordinated dishonesty," *id.* at *26; *see also Margolies v. Rudolph*, No. 21-cv-2447, 2023 WL 6151514, at *8 (E.D.N.Y. Sept. 20, 2023) ("plaintiff cannot establish actual malice on the basis that a defendant declined to consider plaintiff's account").

<u>"Confirmatory" Studies by Dr. Wang and Dr. Burns.</u> Cassava also supplements the FAC by adding allegations based on three articles or presentations co-authored by Dr. Wang and Dr.

Burns from May, June, and September 2023 (Exs. 4, 5, 191). None refutes or contradicts anything in the Dot.com Defendants' statements.

- Exhibit 4 ("A novel filamin A-binding molecule may significantly enhance SST2 antitumoral actions in GH-secreting PitNET cells," dated May 2023): Cassava claims this abstract reflects an "independent" and "confirmatory study relating to simufilam" by a team at the University of Milan (see SAC ¶¶ 115-116, 561.q, 568.a, 607). In fact, it does not concern Alzheimer's disease; it does not show that simufilam is capable of binding to filamin A; and it does not replicate any of the anomalous (and missing) data questioned by the Dot.com Defendants. The article is co-authored by Dr. Burns.
- Exhibit 191 ("Simufilam suppresses overactive mTOR and restores its sensitivity to insulin in Alzheimer's disease patient lymphocytes," dated June 2023): Cassava claims this article provided "a valid scientific basis for simufilam's potential to treat disease" that "contradicts" the Dot.com Defendants' statements. (SAC ¶¶ 568.b, 528, 538.) The study does not show that simufilam is capable of binding to filamin A; and it does not replicate any of the anomalous (and missing) data questioned by the Dot.com Defendants. It is co-authored by Dr. Wang and Dr. Burns. Moreover, the Dot.com Defendants and others have raised concerns about the study's blinding methods, missing data, and Western blot images.³¹
- Exhibit 5 ("Simufilam Reverses Aberrant Receptor Interactions of Filamin A in Alzheimer's Disease," dated September 2023): Cassava describes this article as an "independent" study by the Cochin Institute that "directly confirmed prior research findings regarding simufilam's effect on the Alzheimer's disease mechanism." (*See* SAC ¶¶ 117-121, 529, 539, 568.e, 568.c, 607). In fact, the study does not directly measure simufilam's ability to bind to filamin A, but rather, offers "hypothesized" results concerning simufilam's interaction with filamin A. It does not replicate any of the anomalous (and missing) data questioned by the Dot.com Defendants. The article is coauthored by Dr. Wang and Dr. Burns, and "funded by Cassava." (Ex. 5 at 15.) Non-party scientists have raised concerns about the study's data and Western blot images.³²

"Confirmatory" Articles by Other Scientists. Cassava further supplements its pleadings by submitting four articles co-authored by other researchers, published between May 2022 and May 2023 (Exs. 186-189), which are allegedly "confirmatory" of the science underlying simufilam. A cursory review of these Exhibits shows they are not even relevant, let alone

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³¹ See Comments to Exhibit 191, PubPeer, https://pubpeer.com/publications/B42F8B520CD0ED4C4DE3B1B6AA52EA#1

³² See Comments to Exhibit 5, *PubPeer*, https://pubpeer.com/publications/1751722D4C129D8878A4D457FD00AC#6

directly contrary to any of the Dot.com Defendants' statements or critiques. None of these additional studies examines simufilam or its purported link to filamin A.

- Exhibit 186 is an article by a group of Japanese scientists, published on May 25, 2022, that studies the effects of filamin A on tau pathology. (See SAC ¶ 561.m.) The paper cites—but by no means "confirms"—certain papers authored by Dr. Burns and Dr. Wang. It does not claim or offer evidence of a connection between filamin A and Alzheimer's disease. It does not mention simufilam.
- Exhibit 187 is an article by a group of Canadian scientists, published on November 24, 2022. (See SAC ¶ 561.n.) It reports correlations between an insoluble form of filamin A and samples from Alzheimer's disease patients. It has nothing to do with simufilam.
- Exhibit 188 is an article by a group of Canadian scientists, published on November 18, 2022, that studies the effects of filamin-A on tau pathology. (See SAC ¶ 561.o.) It reports an interaction between filamin A and Tau pathology, cites one paper by Dr. Wang and Dr. Burns as background (Ex. 189 at 3, n. 31), while concluding that "more work needs to be done before elaborating therapeutic strategies that target [filamin A] for preventing Tau pathology" (id. at 18). This article also has no mention of simulfilam.
- Exhibit 189 is an article by a group of Chinese scientists, published on February 22, 2023, concerning the expression of filamin A in liver disease. (See SAC ¶ 561.p.) It has nothing to do with Alzheimer's disease, and merely cites one paper by Dr. Wang and Dr. Burns in the discussion section (Ex. 189 at 7, n. 18). There is no mention of simufilam.

Finally, the only "new" category of allegedly "contrary" information in the SAC is Cassava's own pleadings. Cassava claims that "Defendants were aware of accurate information about Cassava and simufilam based on the Complaint and First Amended Complaint filed by Cassava on November 2, 202[2] and November 4, 202[2]." (SAC ¶ 566.) This category is no different from Cassava's press releases and SEC filings, replete with conclusory assertions and "mere denials" that cannot support a finding of actual malice, "especially" in this case, involving widespread concerns over Cassava's potentially "years-long pattern of coordinated dishonesty." *Cassava*, 2024 WL 1347362, at *26.

C. Cassava's Actual Malice Allegations Violate Rule 8(a)

Judge Wang and Judge Woods both found that the FAC violated Rule 8(a). Specifically, Judge Wang determined that Cassava's conclusory assertions, coupled with a pleading "that attaches and incorporates more than 100 exhibits (many of which contain multiple links) and spans nearly 1600 pages, is tantamount to dropping all of the scientific discourse – spanning years of research – in the lap of a randomly selected federal judge." *Cassava Sciences, Inc., v. Bredt, et al.,* (*R&R*), 22-cv-9409, 2024 WL 555484, at *11 (S.D.N.Y. Jan. 3, 2024). Likewise, Judge Woods found that Cassava's "pleadings violate Fed. R. Civ. P. Rule 8(a)" by attaching "dozens of studies," leaving it to the Court to "determine" whether they "conflict[] with Defendants' critiques," and failing to "direct the Court to any specific sections of the articles." *Cassava,* 2024 WL 1347362, at *27 n.48.

Cassava does exactly the same thing in the SAC, to an even worse degree. For example, the SAC provides a list of 34 "contradictory" facts derived from the "the sources referenced above"—an oblique reference to the SAC's 569 preceding paragraphs and 192 Exhibits. (SAC ¶¶ 570-604). Cassava fails to identify which purported "fact" comes from which of the 192 Exhibits (many containing links to other sources). And Cassava makes virtually no effort to identify the particular sections or findings in each source that it is relying on. Cassava's decision to repeat this pleading tactic—despite explicit rebukes by the Court—has imposed considerable costs on the Dot.com Defendants and a needless additional burden on the Court. At minimum, it is grounds for dismissal with prejudice. See United States v. Int'l Longshoremen's Ass'n, 518 F. Supp. 2d 422, 463, n.74 (E.D.N.Y. 2007) (simply pointing to complaint and

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³³ Eleven Exhibits (Exs. 174-185) are not cited at all in the SAC, although the titles of the (irrelevant) articles therein are listed with incorrect Exhibit numbers recycled from the FAC (*see* SAC ¶¶ 561.b-l). Some Exhibits are also duplicates (*see* Exs. 174 and 192; Exs. 3 and 183), while others are mislabeled (*e.g.*, SAC ¶ 561.l (apparently referring to Ex. 185, published in May 2010, miscited as Ex. 92 and mislabeled as a "July 2021 paper")).

attached documents "without identification of which allegations ... apply to which person and for what reason does not provide the type of notice required" under Rule 8(a)).

IV. THE CHALLENGED STATEMENTS ARE NONACTIONABLE

As an initial matter, ten of the challenged statements were not included in the Court's Exhibit A and thus exceed the limited scope of leave granted by the Court. *Compare* Statements 50, 55, 66, and 68-75, *with Cassava*, 2024 WL 1347362, Exhibit A. (*Supra* p. 17.) The SAC's claims as to these ten statements should be dismissed for this reason alone. *See Palm Beach Strategic Income, LP v. Salzman*, 457 F. App'x 40, 43 (2d Cir. 2012) ("District courts in this Circuit have routinely dismissed claims in amended complaints where the court granted leave to amend for a limited purpose and the plaintiff filed an amended complaint exceeding the scope of the permission granted") (collecting cases); *see also Mitchell v. Am. Arb. Ass'n*, No. 17-cv-8566-PAE, 2018 WL 10419732, at *3 (S.D.N.Y. May 17, 2018) ("This Court is authorized to disregard claims that go beyond the scope of the amendment permitted in its [prior] Order."); *Desouza v. Off. of Child. & Fam. Servs.*, No. 18-cv-2463-PKC-SMG, 2019 WL 2477796, at *6 (E.D.N.Y. June 12, 2019) (striking allegations going beyond scope of permitted leave to amend).

In any event, as explained below, all of the challenged statements are nonactionable expressions of pure opinion or scientific discourse. (*See also* **Appendix 1** (providing full text of challenged statements with links to full threads, and summarizing analysis in chart form).)³⁴

A. Gross and ONY Legal Frameworks

The New York Court of Appeals has identified three factors to provide guidance as to whether a statement is fact or opinion:

"especially rigorous" standard for defamation by implication).

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³⁴ These reasons suffice to defeat Cassava's defamation claims whether construed as claims for express defamation or defamation by implication. *See Biro v. Condé Nast*, 883 F. Supp. 2d 441, 466 (S.D.N.Y. 2012) (describing

"(1) whether the specific language in issue has a precise meaning which is readily understood; (2) whether the statements are capable of being proven true or false; and (3) whether either the full context of the communication in which the statement appears or the broader social context and surrounding circumstances are such as to signal readers or listeners that what is being read or heard is likely to be opinion, not fact."

Cassava, 2024 WL 1347362, at *7 (quoting Gross v. N.Y. Times Co., 82 N.Y.2d 146, 153 (1993))).

The "dispositive inquiry in distinguishing actionable assertions of fact from protected expressions of opinion is whether a reasonable reader could have concluded that the publications were conveying facts" about the plaintiff. *Valley Elecs. AG v. Polis*, No. 21-2108-CV, 2022 WL 893674, at *1 (2d Cir. Mar. 28, 2022) (citing *Gross*, 82 N.Y.2d at 152). Instead of "sifting through a communication for the purpose of isolating and identifying assertions of fact," courts "consider the broader written and social contexts of the alleged statements, which are often the key consideration[s] in categorizing a statement as fact or opinion." *Id*.

Notably, under New York law:

"even . . . accusations of criminality could be regarded as mere hypothesis and therefore not actionable if the facts on which they are based are fully and accurately set forth and it is clear to the reasonable reader or listener that the accusation is merely a personal surmise built upon those facts. In all cases, whether the challenged remark concerns criminality or some other defamatory category, the courts are obliged to consider the communication as a whole, as well as its immediate and broader social contexts, to determine whether the reasonable listener or reader is likely to understand the remark as an assertion of provable fact."

Cassava, 2024 WL 1347362, at *11 (quoting Gross, 82 N.Y.2d at 155) (emphasis added)

"Pure opinion is a 'statement of opinion which is accompanied by a recitation of the facts upon which it is based' or does not imply that it is based on undisclosed facts" known only by the author. *Cassava*, 2024 WL 1347362, at *7 (quoting *Chau*, 771 F.3d 129).

Moreover, in *ONY*, the Second Circuit acknowledged that "[s]cientific academic discourse poses several problems for the fact-opinion paradigm of First Amendment jurisprudence." *ONY, Inc. v. Cornerstone Therapeutics, Inc.*, 720 F.3d 490, 496 (2d Cir. 2013). While the "very premise of the scientific enterprise" is that it "engages with empirically verifiable facts about the universe," it is also "the essence of the scientific method that the conclusions of empirical research are tentative and subject to revision, because they represent inferences about the nature of reality based on the results of experimentation and observation." *Id.* Where "a statement is made as part of an ongoing scientific discourse about which there is considerable disagreement, the traditional dividing line between fact and opinion is not entirely helpful." *Id.* at 497. Therefore, where a "speaker or author draws conclusions from non-fraudulent data, based on accurate descriptions of the data and methodology underlying those conclusions, on subjects about which there is legitimate ongoing scientific disagreement," those statements are not actionable. *Id.; see also Cassava*, 2024 WL 1347362, at *8.

B. The 74 Challenged Tweets Are Nonactionable

All of the challenged Tweets are either nonactionable pure opinion under *Gross* or nonactionable scientific discourse under *ONY*, when considered in their broader and immediate contexts, which includes, at minimum, the Citizen Petition, the Dot.com Defendants' websites, FDA Letter, Slide Decks, Twitter profiles, prior Tweets, \$SAVA hashtag, and complete threads.

1. Viewed in Context, the Challenged Tweets Echo the FDA Letter and Slide Decks and Are Thus Nonactionable for the Same Reasons

All of the challenged Tweets post-date the Citizen Petition, and virtually all post-date the Dot.com Defendants' FDA Letter and Slide Decks.³⁵ Thus, the challenged Tweets cannot be

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³⁵ The only possible exception is Statement 1, which was posted on or around the same time as the FDA Letter.

divorced from the Citizen Petition and the Dot.com Defendants' previously published critiques, which provided the backdrop for all of their subsequent debates on Twitter. *See Cassava*, 2024 WL 1347362, at *17 (recognizing that the "broader context" of the Dot.com Defendants' slide decks included the "the Dot Com Defendants' websites along with the Dot Com FDA Letter" conveying that they were "opinions and scientific inference"); *see also Cooper v. Templeton*, 629 F. Supp. 3d 223, 236 (S.D.N.Y. 2022) (considering challenged Tweet in context of related viral video and "dialogue surrounding it both in the media and on social media"); *Gisel v. Clear Channel Comme'ns, Inc.*, 94 A.D.3d 1525, 1527 (4th Dep't 2012) (considering challenged statements in context of "facts that were widely reported" and defendant's prior radio shows in which he "engaged his listeners in similar debates regarding plaintiff's culpability on several previous occasions"); *Silvercorp Metals Inc. v. Anthion Mgmt. LLC*, No. 150374/2011, 36 Misc. 3d 1231(A), 2012 WL 3569952, at *9 (N.Y. Sup. Ct. Aug. 16, 2012) (considering allegations of fraud "in the full context of letters and postings and in the broader social context in which such letters and postings were published").

In fact, the challenged Tweets are akin to the "headings and summaries" in the FDA

Letter and Slide Decks, which the Court deemed nonactionable for the same reasons as the

content to which they referred. *See Cassava*, 2024 WL 1347362, at *13 ("the alleged

defamatory nature of these statements hinges on a determination that the underlying statements
they summarize are defamatory"). And the Court already recognized that the Defendants "tweets
expressed many of the same sentiments that appear in the other publications." *Id.* at *3. Now,
with additional context, it is clear that all of the challenged Tweets merely echo the Dot.com

Defendants' scientific conclusions and opinions in the FDA Letter and Slide Decks. Therefore,
they are nonactionable both as pure opinions under *Gross* and scientific discourse under *ONY*.

See Eros Intern. PLC v. Mangrove Partners, No. 653096/2017, 2019 WL 1129196, at *9 (N.Y. Sup. Ct. Mar. 8, 2019) ("Because the Court has found that the underlying articles are not defamatory, tweets that do nothing more than broadcast those articles do not take on a defamatory character.")

In context, every challenged Tweet is recognizable as a summary or reference to the Dot.com Defendants' core critique that Cassava and Dr. Wang manipulated or fabricated the research and laboratory data underlying simufilam's purported mechanism and effects (*see*, *e.g.*, Statements 19 and 50). The critique has merely been adapted to comply with the rules of engagement on Twitter, including its 280-character limit and rhetorical tone. Hence, the tag line "it's all made up" (*see* SAC ¶¶ 133). Accordingly, the challenged Tweets are nonactionable for the same reasons as the Dot.com Defendants' underlying critiques in the FDA Letter and Slide Decks.

2. Viewed in Context, Reasonable Readers Would Understand the Challenged Tweets as Opinions

i. The \$SAVA Hashtag and Nature of Debates Using the Hashtag Conveyed that the Challenged Tweets Were Opinions

In *every* challenged Tweet or its accompanying thread, the Dot.com Defendants used the \$SAVA hashtag, which linked to other Tweets about Cassava and placed the statements within a long-running debate among critics and defenders of Cassava, including Cassava investors, scientists, and short sellers. *See Ganske v. Mensch*, 480 F. Supp. 3d 542, 545 (S.D.N.Y. 2020) (considering challenged Tweet in context of other Tweets on the same day); *Eros Intern. PLC*, 2019 WL 1129196, at *10 (considering Defendants' Twitter profile as a whole, including bio, which signaled that statements were opinions); *Jacobus v. Trump*, 51 N.Y.S.3d 330, 342 (N.Y. Sup. Ct. 2017) (considering nature of defendant's "regular use of Twitter" as contextual factor conveying that statements were opinions), *aff'd*, 64 N.Y.S.3d 889 (1st Dep't 2017).

The use of the \$SAVA hashtag signaled that the challenged Tweets were the Dot.com Defendants' opinions, expressed amid fiery and hyperbolic debates over simufilam's legitimacy and the value of Cassava's stock. For example, the thread containing Statements 60 to 62 began when one of Cassava's defenders and an active \$SAVA participant accused the Dot.com Defendants and others of "perpetrating a genocide" against Alzheimer's patients by criticizing Cassava. (See Exs. 65-67 (hyperlinks show full thread).) These debates also involved frequent posts of comedic images or gifs, with a sarcastic and mocking tone (see, e.g., Statements 3, 49, 59). Thus, in this context, Tweets asserting or implying "fraud" and that simufilam's underlying science is "made up" or "faked" (see, e.g., Statements 5, 14, 43) are "exactly the type of loose, figurative or hyperbolic statements, that [] are not actionable." MiMedx Grp., Inc. v. Sparrow Fund Mgmt. LP, No. 17-cv-07568, 2018 WL 847014, at *7 (S.D.N.Y. Jan. 12, 2018) (finding allegations of "fraud" nonactionable pure opinion), report and recommendation adopted, 2018 WL 4735717 (S.D.N.Y. Sept. 29, 2018); Deer Consumer Products, Inc. v. Little Group, No. 650823/2011, 2012 WL 5983641, at *20 (N.Y. Sup. Ct. Nov. 29, 2012) (considering allegation of "fraud" nonactionable in immediate context of online blog and broader context of ongoing SEC investigation); Nanoviricides, Inc. v. Seeking Alpha, Inc., No. 151908/2014, 2014 WL 2930753, at *5 (N.Y. Sup. Ct. June 26, 2014) (considering allegation of business "fraud" as nonactionable pure opinion about "business practices and its stock value").

Reasonable readers would easily recognize the challenged Tweets as the kind of freewheeling exchange of opinion that routinely occurs on Twitter. *See, e.g., Valley Elecs. AG v. Polis*, No. 20-cv-2133, 2021 WL 3919244, at *8 (E.D.N.Y. Aug. 6, 2021) (considering statement on Twitter that, although "is itself an objectively verifiable statement of fact," in context of Twitter back-and-forth would be understood as "an exchange of views, not an assertion of fact"),

aff'd, 2022 WL 893674; see also Pelkowski v. Hovermann, No. 20-cv-1845, 2021 WL 9032222, at *5 (E.D.N.Y. Sept. 9, 2021) (dismissing defamation claim based on Instagram posts accusing plaintiff of theft, where "context and tone of the post itself suggest snarky opinion" and "bolstered by . . . string of hashtags, colorful emojis, and snarky writing."); Yangtze River Port and Logistics Ltd. v. Research, No. 150721/2019, 2020 WL 905770, at *7 (N.Y. Sup. Ct. Feb. 25, 2020) (dismissing defamation claim against short sellers based on statements on Yahoo Finance, Twitter, Hacker News and Reddit).

ii. Additional Contextual Factors Conveyed that the Challenged Tweets Were Opinions

Under the *Gross* framework, reasonable readers would have understood each Tweet as opinion for several additional reasons (*see also* **Appendix 1**).

First, many challenged Tweets used subjective and imprecise terms or phrases, including Statement 1 ("photoshopping"); Statements 2 and 20 ("garbage"); Statements 11, 21, 58, 61, and 65 ("charade"); Statements 22, 45, and 49 ("scam"); Statement 24 ("shitshow"); Statements 31, 49, 52, 53, 57 ("pump-and-dump" or "pump"); Statement 46 ("poster boy"); Statement 56 ("perfect fit"); Statement 60 ("fabulist"); and Statement 69 ("fantastical"). See Cassava, 2024 WL 1347362, at *16 (noting that the word "creatively" has no "precise meaning," and is not capable of being "proven true or false") (citing Gross, 82 N.Y.2d at 153).

Second, many challenged Tweets contained qualifying and other opinion-like language, including Statements 8 ("it appears"), 26 ("it looks like"), 27 ("I think"), 53 ("apparently"), 54 ("imo [in my opinion]" and "seems to me"), 71 ("reasonable inference and implication"), 72 ("allegedly"), and 74 ("in my scientific opinion"). See Schmitt v. Artforum Int'l Magazine, Inc., 115 N.Y.S.3d 291, 301 (1st Dep't 2019) (finding that "hedged phrasing also does not present falsifiable statements of fact"); Bellavia Blatt & Crossett, P.C. v. Kel & Partners LLC, 151 F.

Supp. 3d 287, 293 (E.D.N.Y. 2015) (noting that qualifier words "signal presumptions and predictions rather than facts") (collecting cases), *aff* 'd, 670 F. App'x 731 (2d Cir. 2016) (summary order).

Third, many challenged Tweets contained speculations or predictions of future consequences, conveying that the statements were opinions. See, e.g., Levin v. McPhee, 119 F.3d 189, 197 (2d Cir. 1997) ("When the defendant's statements, read in context, are readily understood as conjecture, hypothesis, or speculation, this signals the reader that what is said is opinion, and not fact."). For example, Statements 6 and 12 made predictions about Cassava's stock price; Statements 9 to 12 predicted the failure of simufilam's clinical trials; Statement 43 predicted that Cassava would "have its rug pulled any day"; Statement 58 predicted that Cassava is "going to come crashing down"; and Statement 64 speculated about Dr. Wang and Cassava executives going "to jail."

Fourth, many challenged Tweets contained calls for investigation, conveying that the statements were opinions. See, e.g., Brian v. Richardson, 87 N.Y.2d 46, 54 (1995); Silvercorp Metals Inc. v. Anthion Mgmt. LLC, No. 150374/2011, 2012 WL 3569952, at *2 (Sup. Ct. Aug. 16, 2012). For example, Statement 17 copied the SEC's Twitter account and Statement 26 copied the editor of the Journal of Neuroscience to express frustration and the need for further investigation. (See also Statements 13, 17, 22, 26, 47.)

Fifth, many challenged Tweets or threads referenced the Dot.com Defendants' short positions, conveying that the statements were opinions, including Statements 2, 3, 16, 35, 55, 57, 58, and 60-62. See Silvercorp Metals Inc., 2012 WL 3569952, at *2 (finding that a defendant's disclosure of his short position "indicates [to the reader] that the author is expressing his opinion"); see also Cassava, 2024 WL 1347362, at *14.

For these reasons, reasonable readers would easily recognize all of the challenged Tweets as opinions. Accordingly, "the court must next determine whether the statement is 'pure opinion' (and thus non-actionable) or 'mixed opinion' (and therefore actionable)." *Cassava*, 2024 WL 1347362, at *7 (quoting *Chau*, 771 F.3d at 129).

3. In Context, the Challenged Tweets Either Disclose Their Factual Bases or Do Not Imply a Basis in Undisclosed Facts

All of the challenged Tweets are pure opinion because, in context, they either disclosed their factual bases or did not imply a basis in undisclosed facts known only to the Dot.com Defendants.

i. The Dot.com Defendants Disclosed Their Factual Bases

The Dot.com Defendants' factual bases for the challenged Tweets include the FDA Letter, Slide Decks, and "the sources on which those publications were based." *Cassava*, 2024 WL 1347362, at *24 n.43.

It is undisputed that the Dot.com Defendants were repeatedly "posting links" on Twitter to cassavafraud.com, which were, in turn, "reposted and shared extensively," disclosing the factual bases of their opinions (*see, e.g.,* SAC ¶ 652). Indeed, Dr. Heilbut's Twitter profile links to a website that directs users to cassavafraud.com; Statements 6, 14, 19, and 29 contained links to cassavafraud.com in the same thread, and the Dot.com Defendants posted links to their website dozens of time over the same period as the challenged Tweets. (*See* SAC ¶ 132; *supra* p. 15 n.24.) Moreover, the Dot.com Defendants often screenshotted specific slides or images from their sources, directing readers to the specific and most relevant passages (*see, e.g.,* Statements 1, 6-10, 14, 15, 17-24, 26, 28-30, 34-35, 37-42, 45-46, 48, 50-54, 56, 59, 67-75).

Thus, by repeatedly referring or linking to such sources on Twitter, the Dot.com

Defendants disclosed the facts on which the challenged Tweets were based. *See, e.g., Ganske*,

480 F. Supp. 3d at 554 (finding that hyperlinks are an appropriate means of disclosing factual bases); *Paladino v. Cojocaru*, No. 156016/2020, 2022 WL 5004397, at *12 (N.Y. Sup. Ct. Oct. 4, 2022) ("The facts upon which the comparison is made are also stated elsewhere in the thread" and "include a link to the [underlying] Article"); *Straka v. The Lesbian Gay Bisexual & Transgender Community Center, Inc.*, No. 155961/2019, 2020 WL 3578440, at *19 (N.Y. Sup. Ct. July 1, 2020) (finding that "a remark which is prompted by or responsive to a hyperlink . . . is accompanied by a recitation of the facts upon which it is based" and thus pure opinion).

ii. <u>The Dot.com Defendants Never Implied Their Statements Were Based</u> <u>On Undisclosed Facts Known Only by Them</u>

Even where isolated Tweets or threads did not include hyperlinks or screenshots, the challenged Tweets are nonactionable pure opinions because they did not imply that they were based on undisclosed facts known only to the Dot.com Defendants.

As the challenged Twitter threads demonstrate, the Dot.com Defendants' audience comprised of individuals following the \$SAVA hashtag—namely, other scientists and critics of Cassava, as well as Cassava investors and short sellers. (See SAC ¶ 134.) No reasonable reader could have gotten the impression that the Dot.com Defendants were expressing views based on secret undisclosed facts known only to them. To the contrary, viewed in context, the Dot.com Defendants were committed to disclosing and repeating the bases for their opinions as a means of debating and persuading other followers of the \$SAVA hashtag. See Cooper, 629 F. Supp. at 236 (considering widespread dissemination of background facts related to viral video in determining that Tweet could not be construed as implying a basis in undisclosed facts); Gisel, 94 A.D.3d at 1527 (statements based on previously reported facts deemed nonactionable as pure opinions).

Finally, Cassava has failed to plead any statements of opinion "based on false facts" that were expressed with "knowledge of [their] falsity or probable falsity." *Cassava*, 2024 WL 1347362, at *7 (citing *Restis v. Am. Coal. Against Nuclear Iran, Inc.*, 53 F. Supp. 3d 705, 719 (S.D.N.Y. 2014) (citing *Davis*, 754 F.2d at 86). Any effort to allege that the challenged Tweets are actionable under this alternate theory would nevertheless fail because Cassava does not and cannot plead either falsity (*supra* Section II) or actual malice (*supra* Section III).

C. The Statement in the "Seeing Through the Blind" Deck Is Nonactionable

Cassava challenges the following statement in the Seeing Through the Blind Deck:

Emails retrieved from a FOIL request to CUNY expose Cassava and the Wang lab as being unblinded during sample analysis, prior to data presentation and while study is ongoing.

* * *

Hence, whether a patient is ON or OFF the drug is known to the person analyzing samples. This could allow Wang to decide what sample measurements "should be."

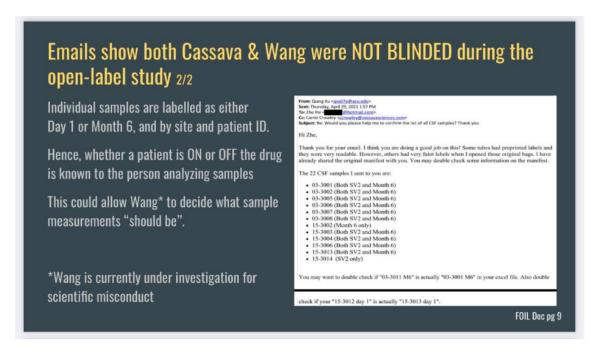
(Statement 23, Ex. 28 at 4-5; see SAC ¶¶ 255-259.)

The Court previously found that the assertion that Dr. Wang was "reveal[ed] to be unblinded during the Open Label Study" could be interpreted as a factual and defamatory statement. *Cassava*, 2024 WL 1347362, at *17-18.

However, Cassava does not and cannot plead that Statement 23 is false or otherwise actionable. In the Open Label Study, *all of the patients in the study received simufilam*. Thus, contrary to the SAC's assertions, there was no question (and the Dot.com Defendants never raised any question) as to whether "the laboratory conducting the test knew if it was testing results for patients who took the placebo or simufilam" (SAC ¶ 255), because there was no placebo group for this study. Rather, the issue was whether the lab analyzing the samples was blind to the *timepoint* at which the sample was collected—that is, (i) before the simufilam

treatment began (labeled as "SV2" aka Screening Visit 2), or (ii) six months after starting simufilam (labeled "MONTH 6"). Cassava knew that this was a critical control necessary to ensure the integrity of the data analysis; indeed, Cassava asserted in its public presentation of this data that the lab analyzing these samples was "blind to timepoint" (Ex. 28 at 2).

The basis for Statement 23's assertion that Cassava and the Wang lab had been "exposed as unblinded" is the email on slide 5 of the Deck. (Ex. 28 at 5 (reproduced below.) That email states that all samples sent to Dr. Wang's lab, where the samples were analyzed, were labeled by time point ("SV2" or "MONTH 6"), contrary to Cassava's assertion that such analysis was done "blind to timepoint."



(Ex. 28 at 5.)

The SAC does not allege that the Open Laby Study was blinded as to timepoint, and thus Cassava fails to plead falsity for Statement 23. Even if Cassava had pleaded falsity, the statement would be protected under *ONY* as scientific discourse and *Gross* as a pure opinion based on disclosed facts (*e.g.*, the email obtained via FOIL described on Ex. 28 at 5).

D. Dr. Heilbut's October 2022 Testimony Is Nonactionable

The SAC includes a cursory reference to Dr. Heilbut's testimony at a public hearing held by CUNY in October 2022. (SAC ¶ 22 (Ex. 2 at 22-24).) The testimony is mentioned only in the jurisdiction section of the SAC, and Cassava fails to allege how it could plausibly give rise to a claim for defamation. In fact, the testimony did not mention Cassava whatsoever. (*Id.*) It is well-established that a plaintiff cannot ground a claim for defamation in statements that are not "of and concerning" the plaintiff. *See Gilman v. Spitzer*, 902 F. Supp. 2d 389, 396 (S.D.N.Y. 2012) (dismissing claim based on statements about plaintiff's employer and unspecified employees but not plaintiff specifically), *aff'd*, 538 F. App'x 45 (2d Cir. 2013). Moreover, even if Dr. Heilbut's testimony could properly be described as "of and concerning" Cassava, the statements fall outside the scope of leave granted by the Court, and would nevertheless be protected as scientific discourse under *ONY* and pure opinion under *Gross*, considering that the testimony was conveyed as a call for investigation into Dr. Wang and did not imply a basis in undisclosed facts.

In sum, the SAC fails to plead an actionable statement made with actual malice, and the defamation claims should therefore be dismissed with prejudice.

V. THE CONSPIRACY CLAIM FAILS AS A MATTER OF LAW

New York law does not recognize an independent tort of conspiracy, and courts specifically reject the notion of a tort of conspiracy to defame. *Dobies v. Brefka*, 694 N.Y.S.2d 499, 501 (3d Dep't 1999). The conspiracy claim fails because Cassava cannot plead an underlying tort claim. *See id.; see also McGill v. Parker*, 582 N.Y.S.2d 91, 105 (1st Dep't 1992) (noting that "the allegation of conspiracy is allowed only to connect a defendant to an otherwise cognizable tort"). Nor does Cassava adequately plead an agreement among the Dot.com

Defendants to defame Cassava. *See Watson v. NY Doe 1*, 439 F. Supp. 3d 152, 167 (S.D.N.Y. 2020); *see also Kirch v. Liberty Media Corp.*, 449 F.3d 388, 401 (2d Cir. 2006).

CONCLUSION

For the foregoing reasons, Drs. Brodkin, Heilbut, and Milioris respectfully submit that the SAC should be dismissed with prejudice. The Dot.com Defendants expressly reserve all rights to seek every available remedy related to this strategic lawsuit against public participation, including recovery under New York's anti-SLAPP law of costs and attorney's fees, other compensatory damages, and punitive damages. *See* N.Y. Civ. Rights Law § 70-a; *see also Watson v. NY Doe 1*, 2023 WL 6540662, at *5 (S.D.N.Y. Oct. 6, 2023).

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